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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/522,753	03/10/2000	Ronald M. Evans	SALK1510-3	4924

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EXAMINER

LEFFERS JR, GERALD G

ART UNIT	PAPER NUMBER
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1636

DATE MAILED: 04/20/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

**Office Action Summary**

Application No.

09/522,753

Applicant(s)

EVANS ET AL.

Examiner

Gerald G Leffers Jr., PhD

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 16 January 2004.
- 2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 3-5, 9, 10, 12-14, 16-25 and 38 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 3-5, 9, 10, 12-14, 16-25 and 38 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 16 January 2004 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☒ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)  
Paper No(s)/Mail Date \_\_\_\_\_
- 4) ☐ Interview Summary (PTO-413)  
Paper No(s)/Mail Date. \_\_\_\_\_
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: \_\_\_\_\_

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### **DETAILED ACTION**

Receipt is acknowledged of an amendment, filed 7/14/2003, in which several claims were amended (claims 4-5, 9, 12, 14 and 18). Claims 3-5, 9-10, 12-14, 16-25 and 38 remain pending in the instant application and are all under consideration at the present time.

Any rejection of record in previous office actions not addressed herein is withdrawn. This action is not final due to new grounds of rejection made herein that were not necessitated by applicants' amendment of the claims in the response filed 7/14/2003.

### ***Oath/Declaration***

The oath or declaration is defective. A new oath or declaration in compliance with 37 CFR 1.67(a) identifying this application by application number and filing date is required. See MPEP §§ 602.01 and 602.02.

The oath or declaration is defective because:  
It was not executed in accordance with either 37 CFR 1.66 or 1.68. The signature for inventor Chen is missing.

Applicants continue to respond that this informality will be handled under different cover. Until such time as a substitute declaration comprising inventor Chen's signature is received, the objection stands.

### ***Drawings***

Receipt is also acknowledged of replacement drawings filed 1/16/2004 in response to a Notice of NonResponsive Amendment mailed 9/23/2003. The drawings are acceptable.

***Claim Rejections - 35 USC § 112***

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 3-5, 9-10, 12-14, 16-25 & 38 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. **This is a new rejection.**

Claims 4, 5, 9, 12, 14 are directed to isolated polynucleotides encoding an SMRT co-repressor protein wherein the co-repressor has at least 80% identity to a reference amino acid sequence. The claims are indefinite with regard to the phrase "or a peptide portion thereof". As written it is unclear whether the nucleic acid encodes *only* the peptide portion of the SMRT co-repressor or *can encode the peptide portion as part of a larger polypeptide sequence*. For example, the claim can reasonably be interpreted to specify only that the nucleic acid encodes a polypeptide portion of an SMRT having at least 80% identity to a reference polypeptide, without any limitation as to additional amino acid sequences surrounding the "polypeptide portion" in the context of a larger protein (see the rejections below for lack of written description and anticipation by the prior art). Alternatively, one might construe the limitation in the context of the claim to mean that the nucleic acid encodes *only* the "polypeptide portion". The two possibilities are not compatible and it would be remedial to amend the claim language to clearly delineate between the two possibilities.

Claim 14 is vague and indefinite in that there is no clear and positive prior antecedent basis for the term "said first polynucleotide".

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Claims 23 and 25 are vague and indefinite in that they recite the limitation that an isolated oligonucleotide hybridizes "specifically" to a reference polynucleotide. The term "specifically" does not appear to be well defined in the specification to indicate explicitly what degree of non-specific hybridization would make a given oligonucleotide not meet the limitation of hybridizing "specifically".

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 3-5, 9, 12, 14, 19, 21-25 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. **This is a new rejection.**

Claims 4, 5, 9, 12, 14 are directed to isolated polynucleotides encoding an SMRT co-repressor protein wherein the co-repressor has at least 80% identity to a reference amino acid sequence. The claims are indefinite with regard to the phrase "or a peptide portion thereof". As written it is unclear whether the nucleic acid encodes *only* the peptide portion of the SMRT co-repressor or *can encode the peptide portion as part of a larger polypeptide sequence*. For example, the claim can reasonably be interpreted to specify only that the nucleic acid encodes a polypeptide portion of an SMRT having at least 80% identity to a reference polypeptide, without any limitation as to additional amino acid sequences surrounding the "polypeptide portion" in the

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context of a larger protein. First, there does not appear to be literal support in the specification as originally filed for such a limitation, making the cited limitation impermissible NEW MATTER.

Second, this interpretation of the limitation “or a peptide limitation thereof” as written in the rejected claims makes the claim read on literally *any* polynucleotide encoding *any* protein. For example, the claimed nucleic acid can encode a peptide portion (e.g. any two or more consecutive amino acids) of any protein that has at least 80% identity to a given reference sequence (e.g. SEQ ID NO: 5). The phrase “at least 80% identity to SEQ ID NO: 5”, for example, encompasses any embodiment where any di-peptide sequence from literally any protein is tacked onto the amino acid sequence of SEQ ID NO: 5 (~2,500 amino acid residues). As indicated above, there is no limitation in the claims as written that the nucleic acid encodes only the “peptide portion” of the SMRT. Thus, the claims literally read on any nucleic acid encoding any protein sequence comprising any amino acid sequence that can be found in the reference sequence (e.g. SEQ ID NO: 5). There is no basis provided in the specification or prior art for the skilled artisan to envision a representative number of specific embodiments to describe the broadly claimed genus of nucleic acids encoding literally *any* protein.

### ***Claim Rejections - 35 USC § 102***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

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Claims 4, 5, 9, 12 are directed to isolated polynucleotides encoding an SMRT co-repressor protein wherein the co-repressor has at least 80% identity to a reference amino acid sequence. The claims are indefinite with regard to the phrase "or a peptide portion thereof". As indicated above, the rejected claims can reasonably be interpreted to specify only that the nucleic acid encodes a polypeptide portion of an SMRT having at least 80% identity to a reference polypeptide, without any limitation as to additional amino acid sequences surrounding the "polypeptide portion" in the context of a larger protein. Thus, the claims literally read on any nucleic acid encoding any protein sequence comprising any amino acid sequence that can be found in the reference sequence (e.g. SEQ ID NO: 5).

Claims 4-5, 9, 12, 19, 21-22 are rejected under 35 U.S.C. 102(e) as being anticipated by Takashima et al (U.S. Patent No. 6,248,559 B1; see the entire patent). **This is a new rejection.**

Takashima et al teach nucleic acid sequences encoding the human Tau-protein kinase 1 protein (HTPK-1), vectors comprising the sequences and host cells comprising the vectors (e.g. Figure 2, Example 3).

### ***Conclusion***

No claims are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Gerald G Leffers Jr., PhD whose telephone number is (571) 272-0772. The examiner can normally be reached on 9:30am-6:00pm.

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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Remy Yucel can be reached on (571) 272-0781. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Gerald G Leffers Jr., PhD  
Primary Examiner  
Art Unit 1636

ggl

  
GERRY LEFFERS  
PRIMARY EXAMINER